K073317

SEP - 3 2008

SECTION G – 510(k) SUMMARY

510(k) Summary of Safety and Effectiveness for STARLIGHT®

Applicant	F. P. Rubinstein y Cía. SRL
Address	David Luque 519 – X5004AKM Córdoba, Argentina
Contact Person	Haydée N. Demarco (Official Correspondent)
Telephone / Fax	+54 351 424 0051 / +54 351 424 7750
Preparation Date	October 29th, 2007
Device Trade Name	STARLIGHT®
Common Name	Intense Pulsed Light System
Classification Name	Laser surgical instrument for use in General and Plastic Surgery and Dermatology - 21 CFR §878.4810 Product Code: GEX Panel: 79 Class: II
Legally marketed Predicate Device	Skin Station™ System, K030897
System Description	STARLIGHT® is a light-based system that delivers Intense Pulsed Light in the region of 530 to 1200 nanometers of the Electromagnetic Spectrum. The system has been designed to be compact and self-contained, comprising: -A central module -An LCD and soft-touch keyboard interface -Two application handpieces housing a flash lamp, a light conducting glass w/filter and two shooting buttons -An integrated Hydraulic Cooling System The system's electronics and user interface are controlled by a microcontroller.
Intended Use	STARLIGHT® is a light-based system intended for the removal of unwanted hair (permanent hair reduction*) and the treatment of benign cutaneous, vascular and pigmentary lesions in skin phototypes I to V of the Fitzpatrick Table. **Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regime.*
Technological Characteristics	The technological characteristics, performance, intended use, indications, operation and application of STARLIGHT® are similar to those of the predicate device; therefore no new questions on safety and effectiveness are raised and a substantial equivalence is determined.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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F.P. Rubinstein y Cía. SRL
% Haydée N. Demarco
David Luque 519
Cordoba X5004 AKM
Argentina

Re: K073317
Trade/Device Name: STARLIGHT®
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: August 4, 2008
Received: August 8, 2008

Dear Haydée Demarco:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE
STARLIGHT®

510(k) Number: K073317

Device Name: STARLIGHT®

Indications for Use:

STARLIGHT® is a light-based system intended for the removal of unwanted hair (permanent hair reduction*) and the treatment of benign cutaneous, vascular and pigmentary lesions in skin phototypes I to V of the Fitzpatrick Table.

**Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regime.*

Prescription Use ___X___ OR (per 21 CFR 801.109) Over-the-counter Use _____

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073317